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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,850	BURKE ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/24/2008 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/04/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS of 5/22/2008* .

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of March 24, 2008 ("Amendment") does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed March 24, 2008 have been fully considered but they are not persuasive.

Rejections of claims 1-5 and 16 under 35 U.S.C. 103(a) are being obvious over Neel in view of Beaty and of claim 6 as being obvious under 35 U.S.C. 103(a) over Neel in view of Beaty and Feldman

Claim 1

Applicant asserts, "… Neel teaches that applying a DC signal to the measurement electrodes for purposes of determining dose sufficiency will thereby disturb the reaction between the sample and the reagent in the critical region of the sample chamber for measurement. By applying the DC signal to the dose sufficiency

electrodes separate and distinct from the measurement electrodes, and leaving an open circuit between the measurement electrodes, the stoichiometry of the measurement region is not disturbed until the measurement sequence is ready to begin. See Neel, col. 14, line 55 to col. 15, line 25." See page 8 of the Amendment. The passage Applicant refers to does not make any mention of how a DC signal applied to the dose sufficiency electrodes may disturb the reaction between the sample and the reagent. It justs describes steps for using the sensor in one embodiment. Moreover, even if Neel somewhere else discloses that dose sufficiency electrodes are provided separate from the measurement electrodes to prevent the measurement regions to be disturbed there are other reasons for providing separate does sufficiency electrodes, which will be discussed below.

Applicant asserts, "There is nothing in the combination that would suggest to one of ordinary skill in the art that a signal having an AC component should be applied to separate dose sufficiency electrodes since Beaty demonstrates that this is unnecessary when using an AC signal." See page 9 of the Amendment. Applicant has reversed the rejections. Neel is the base reference and Beaty is the secondary reference. Neel already discloses a pair of dose sufficiency electrodes. Beaty is used to show that it would have been obvious to one with ordinary skill in the art to apply an AC signal instead of a DC signal to the dose sufficiency electrodes in Neel. Beaty makes no reference to the sensor of Neel or to another sensor having separate dose sufficiency electrodes. Beaty does not exclude applying and AC signal to separate dose sufficiency electrodes. Indeed, Beaty discloses that a DC offset to the AC signal may

be useful. See col. 11:32-57 and col. 12:12-19. In such a situation Applicant would surely acknowledge that separate dose sufficiency electrodes would have been obvious since Applicant asserts, as noted above, that Neel allegedly teaches using separate dose sufficiency electrodes to prevent a DC signal from disturbing the reaction between the sample and reagent.

Applicant asserts,

> The Office Action attempts to counter the above teachings by alleging that Neel places the fill-detect electrodes 28 and 30 downstream from the measurement electrodes in order to ensure that 1) the sample has covered the reagent layer and the measurement pair of electrodes, and 2) that the sample has sufficiently mixed with the reagent (Office Action, p. 3). It is respectfully submitted that the teaching of Beaty to apply an AC signal to the measurement electrodes accomplishes (1) above, namely determining that there is adequate sample volume to cover the electrodes and the reagent covering the electrodes - that is the reason that Beaty performs this test. As to point (2), there is no teaching in Neel that the device disclosed therein can actually detect sufficient mixing of the sample and the reagent. Neel is able to determine that the sample has covered the reagent, but he teaches no method of detecting that the sample has sufficiently mixed with the reagent. Despite the portion of the Neel disclosure quoted in the Office Action, one skilled in the art would immediately recognize that there is no teaching in Neel in order to substantiate such a claim. As Beaty also teaches that application of an AC signal to the measurement electrodes can detect adequate sample volume to cover the electrodes and the reagent covering the electrodes, the fill-detect electrodes of Neel would therefore become superfluous in the combination of Neel and Beaty. It is only Applicants' disclosure
>
> See page 9 of the Amendment.

Again, Applicant has reversed the rejections. The Examiner argues that it would have been obvious to one with ordinary skill in the art at the time of the invention to apply an AC signal or AC signal with DC offset to the *dose sufficiency electrodes that are already in Neel*. The Examiner is not arguing for providing separate dose sufficiency electrodes in Beaty. By applying an AC signal to the dose sufficiency

electrodes in Neel other parameters of the sample may be determined, such as "…sample temperature, the concentration of such physical and chemical interferants, the identity of the sample and the sample volume..." See in Beaty col. 06:01-04. The advantage of separate dose sufficiency electrodes is that it still allows a DC signal to be used without fear of disturbing the reaction between the sample and reagent. Such a DC signal may be a DC offset as taught by Beaty to optimally determine an interferant's concentration. See col. 11:31-46. As acknowledged by Applicant, Neel discloses providing separate dose sufficiency electrodes to avoid disturbing the reaction between the reagent and sample, so one with ordinary skill in the art would apply the AC signal with DC offset to the dose sufficiency electrodes. Separate dose sufficiency electrodes would also allow for dose sufficiency to be determined by only a DC signal as taught by Neel, if desired, and for also using an AC signal for the other reasons disclosed by Beaty. Additionally, with separate dose sufficiency electrodes placed downstream of the measurement electrodes as taught by Neel this further ensures that adequate sample has been supplied and has contacted the reagent because sample must travel the through the measurement zone in order to reach the dose sufficiency electrodes. Thus, the separate dose sufficiency electrodes are not superfluous if an AC signal is also used with the sensor of Neel. As for Applicant's second point, whether the sensor of Neel has the ability to detect whether the sample has sufficiently mixed with reagent, Neel mentions this feature in several places in the patent. See col. 05:02-11; col. 08:18-33; and col. 14:63 – col. 15:17. From col. 05:08-11 it appears that adequate

mixing is decided based on the current through the dose sufficiency electrodes is large enough after a predetermined time period.

Citing Applicant's specification page 54, lines 14-29 Applicant asserts an advantage to separate dose sufficiency electrodes to which an AC signal is applied that is not taught by Neel or Beaty, namely avoiding an erroneous sufficiency reading due to a concave flow front. However, Applicant's specification states that this benefit accrues if the dose sufficiency electrodes are configured as shown in Figure 35 ("parallel dose sufficiency electrodes"), not if arranged as shown in Figure 34 ("perpendicular dose sufficiency electrodes"). See the bottom of page 51 of the specification to page 53. Applicant's claim 1 and most of the dependent claims do not require the dose sufficiency electrodes to be configured as shown in Figure 35. Thus, this point is moot. Moreover the dose sufficiency electrodes shown in Neel (Figure 9, for example) resemble those of Applicant's Figure 35 more than those of Applicant's 34. So, if an AC signal was applied to the dose sufficiency electrodes of Neel the same benefit as asserted by Applicant would be expected for the sensor of Neel.

Claims 2-6 and 16

For the rejections of these claims Applicant relies on his arguments against the rejection of underlying claim 1. The Examiner in turn relies on his rebuttal above.

Rejections of claims 7-15 under 35 U.S.C. 103(a) as being obvious over Neel in view of Feldman

Claim 7

Applicant asserts, "… Feldman et al. does not teach or suggest the provision of any type of electrodes for measuring fill time, let alone the provision of a separate set of electrodes for analyte measurement and fill time measurement. Neel et al. actually teaches directly away from the claimed invention by specifying that the measurement electrodes should be used as part of the fill time measurement.' See the bottom of page 11, bridging to page 12 of the Amendment. Applicant has reversed the rejection. In the Examiner's rejections of claims 7-15 Neel, which teaches a first pair of electrodes for measuring analyte and for determining when the sample contacts these electrodes and which also teaches a second pair of electrodes for determining a fill time based on the time difference from when the first pair of electrodes are contacted by the sample to when the second pair of electrodes are contacted by the sample, is modified by Feldman, which teaches providing multiple pairs for measuring electrodes (measurement electrodes and corresponding counter electrodes) so that multiple analytes in the sample can be measured. Feldman is not the base reference in these rejections. Although Neel discloses that the first pair of electrodes is used for both determining the beginning of the fill-time and for measuring an analyte this does not

exclude providing one or more additional pairs of electrodes for measuring other analytes. Providing one or more additional measurement pairs of electrodes is clearly desirable and easily achievable by just patterning more electrodes and associated leads onto the base substrate. Neel and Feldman are clearly analogues are as these references are directed to small, planar electrochemical enzyme tests strips.

Claims 8-11

For the rejections of these claims Applicant relies on his arguments against the rejection of underlying claim 7. The Examiner in turn relies on his rebuttal above.

Claim 12

Applicant's arguments against the rejection of claim 12 is the same as the arguments against the rejection of claim 7. The Examiner in turn relies on his rebuttal above.

Claims 13-15

For the rejections of these claims Applicant relies on his arguments against the rejection of underlying claim 12. The Examiner in turn relies on his rebuttal above.

3. For the reasons set forth above the prior art rejections are maintained.

Status of the Rejections pending since the Office action of November 01, 2007

4. All of the rejections under 35 U.S.C. 103(a) are maintained; the rejections of claims 7 and 12 have been modified in light of Applicant's Amendment. All of the rejections are presented below for Applicant's convenience.

5. All of the rejections of claims 7-11 under 35 U.S.C. 112, second paragraph, are withdrawn.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. (US 6,645,368 B1) ("Beaty").

Addressing claim 1, Neel discloses a method of performing a measurement on a biological fluid in a test strip (abstract) comprising

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake opening (68) to a terminus (70)(Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

and

a second pair of electrodes (28,30) in operative communication with the chamber (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

applying a first test signal to at least one of the first pair of electrodes (col. 14:48-55);

measuring a first response to the first test signal (col. 14:48-55);

maintaining the first pair of electrodes in an inoperative state after the measuring the first response (col. 14:55-57);

applying a second test signal to at least one of the second pair of electrodes

(col. 14:67 – col. 15:03);

measuring a second response to the second test signal (col. 14:67 – col. 15:03); and

performing a measurement upon the biological fluid after the measuring the second response (col. 15:26-28).

The second test signal applied by Neel appears to be just a DC test signal (col. 14:67 – col. 15:03).

Beaty discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip for determining the concentration of a medically significant component of a biological fluid. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel as the second test signal because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit, glucose (or other

analyte) concentration, temperature, bilirubin concentration, uric acid concentration, and oxygen concentration. See 06:20-42.

Addressing claim 2, Neel et al discloses the measuring of the first response to the first test signal is indicative of contact between the first pair of electrodes and the biological fluid (Column 14, lines 48-51).

Addressing claim 3, Neel et al discloses measuring the first response to the first test signal to indicate contact of the first pair of electrodes and the fluid (Column 14, line 63 through Column 15, line 11).

Addressing claim 4, Neel et al discloses measuring the second response to the second test signal to indicate contact of the second pair of electrodes and the fluid (Column 14, lines 48-55).

Addressing claim 5, Neel et al discloses performing a measurement on the biological fluid by applying a test signal to at least one of the first pair of electrodes (Column 15, lines 47-58).

Addressing claim 16, for the additional limitation of this claim note that Beaty teaches that the second test signal may be a pure AC signal or may have a DC offset. See col. 06:20-57 and col. 11:32-36.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. US 6,645,368 B1 ("Beaty") as applied to claims 1-5 and 16 above, and further in view of Feldman et al. US 6,592,745 B1 ("Feldman").

Neel does not mention providing a third pair of electrodes in operative communication with the chamber wherein the performing a measurement upon the

biological fluid includes applying a measurement test signal to at least one of the third pair of electrodes.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair, as taught by Feldman in the invention of Neel as modified by Beaty because as taught by Feldman, "… multiple electrode sensors may be used to test a variety of analytes using a single sample …" and "[m]ultiple electrode sensors may also be used to improve the precision of the resulting readings …". See col. 48:16-59.

9. Claims 7-15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Feldman et al. US 6,592,745 B1 ("Feldman").

Addressing claim 7, Neel discloses a method of indicating acceptable fill time of a biological fluid in a test strip comprising:

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake

opening (68) to a terminus (70) (Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

a second pair of electrodes (28, 30) in operative communication with the chamber (Figure 2) ; and

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

flowing a biological fluid from the opening toward the terminus (col. 14:43-51);

first determining when the biological fluid contacts the first pair of electrodes (col. 14:35-60, step 348 in Figure 17) ;

second determining when the biological fluid contacts the second pair of electrodes

(col. 14:63 – col. 15:11);

determining a fill time value based upon the first determining and the second determining (col. 14:27 – col. 15:11 and steps 348-358 in flowchart in Figure 17); and

comparing the fill time value to a predetermined value (col. 05:02-11).

Neel does not mention providing a third pair of electrodes in operative communication with the chamber and measuring an analyte concentration of the biological fluid using the third electrodes.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair, as taught by Feldman in the invention of Neel as modified by Beaty because as taught by Feldman, "… multiple electrode sensors may be used to test a variety of analytes using a single sample …" and "[m]ultiple electrode sensors may also be used to improve the precision of the resulting readings …". See col. 48:16-59. Note that claim 7 does not exclude the first pair of electrodes from also being used measure another analyte different from the analyte measured with the third pair of electrodes. Thus, with the first pair of electrodes and the third pair of electrodes at least two different analytes in the sample can be measured.

Addressing claims 8 and 9, Neel discloses indicating an error if the fill time exceeds a predetermined value (Column 15, lines 19-24).

Addressing claims 10 and 11, Neel et al discloses performing a measurement on the fluid if the fill time is less than a predetermined value (Column 15, lines 26-32).

Addressing claim 12, Neel discloses a method of performing a measurement on a biological fluid in a test strip (abstract) comprising

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake opening (68) to a terminus (70)(Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

and

a second pair of electrodes (28,30) in operative communication with the chamber (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

applying a first test signal to at least one of the first pair of electrodes (col. 14:48-55);

measuring a first response to the first test signal (col. 14:48-55);

maintaining the first pair of electrodes in an inoperative state after the measuring the first response (col. 14:55-57);

applying a second test signal to at least one of the second pair of electrodes (col. 14:67 – col. 15:03);

measuring a second response to the second test signal (col. 14:67 – col. 15:03);

determining a fill time for the chamber based upon the first response and the second response (col. 14:27 – col. 15:11 and steps 348-358 in the flowchart in Figure 17).

Neel does not mention the steps of applying a measurement test signal to at least one of the third pair of electrodes after the measuring the second response;

measuring a third response to the third test signal; and determining a concentration of an analyte in the biological fluid using the third response.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair and use it for measuring an analyte concentration, as taught by

Feldman in the invention of Neel as modified by Beaty because as taught by Feldman, "… multiple electrode sensors may be used to test a variety of analytes using a single sample …" and "[m]ultiple electrode sensors may also be used to improve the precision of the resulting readings …". See col. 48:16-59. Note that claim 7 does not exclude the first pair of electrodes from also being used measure another analyte different from the analyte measured with the third pair of electrodes. Thus, with the first pair of electrodes and the third pair of electrodes at least two different analytes in the sample can be measured.

Addressing claim 13, for the additional limitation of this claim see in Neel col. 14:35-60, step 348 in Figure 17.

Addressing claim 14, for the additional limitation of this claim see in Neel col. 14:63 – col. 15:11.

Addressing claim 15, for the additional limitations of this claim see in Neel col. 14:27 – col. 15:11 and steps 348-358 in flowchart in Figure 17.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Feldman et al. US 6,592,745 B1 ("Feldman") as applied to claims 7-15 above, and further in view of Beaty et al. US 6,645,368 B1 ("Beaty").

The second test signal applied by Neel as modified by Feldman appears to be just a DC test signal (col. 14:67 – col. 15:03).

Beaty discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip for determining the concentration of a medically significant component of a biological fluid. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel as modified by Feldman as the second test signal because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit, glucose (or other analyte) concentration, temperature, bilirubin concentration, uric acid concentration, and oxygen concentration. See 06:20-42.

Final Rejection

11. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795